K080601

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JUN - 6 2008

COVER LETTER
and
510(k) SUMMARY of ERGO++

February, 28th 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Reference : TRADITIONAL 510(k) for **ERGO++**

Dear Madam/Sir:

The 3D Line Research and Development S.r.l. hereby submits this Traditional 510(k) for our ERGO++ Treatment Planning System. ERGO++ is a modification of ERGO, ERGO SRS and ERGO EVTOOL (3D Line USA, Inc) (K001163, K031281, K013535). The modifications are listed in Appendix 8. We believe these modifications are not eligible for the Special 510 (k) process.

We consider our intent to market this device as confidential commercial information and requests that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intend to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application.

Sincerely,

Marco Luzzara
Managing Director

3D LINE RESEARCH AND DEVELOPMENT S.R.L. – VIA BERNARDO RUCELLAI, 23 – 20126 – MILANO (MI)
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SOCIETA' SOGGETTA A DIREZIONE E COORDINAMENTO DI ELEKTA AB (publ.), STOCCOLMA, SVEZIA –
SOCIO UNICO

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Section 1: required elements for all types of 510(k) submissions

- 510(k) holder name: **3D Line Research and Development S.r.l.**
- address: **Via Bernardo Rucellai, 23, Milano, Italy, 20126**
- phone: +39-02-2550161
- fax: +39-02-25501642
- facility registration number: **9617259**
- Trade name of the device: **ERGO++**
- Common name: **Treatment Planning System**
- Classification Name: system, planning, radiation therapy treatment (21CFR 892 5050, Product Code MUJ)
- Classification: Class II
- name of contact persons: Marco Luzzara
- date the summary was prepared: February, 28th 2008
- A statement of substantial equivalence to ERGO, ERGO SRS and ERGO EVTOOL (3D Line USA, Inc) (K001163, K031281, K013535) manufactured by 3D Line USA, Inc is **Appendix 7** of this notification.
- description of the device such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant

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physical and performance characteristics of the device, such as device design, material used, and physical properties is in **Appendix 2** and **Appendix 3** of this notification.

- the intended use of the device including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended, is in **Appendix 2** of this notification.
- the indication statement is a subset of those of the predicate device. See **Appendix 7** for additional information.
- the conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device are in **Appendix 6** of this notification.

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Section 2: required elements for a TRADITIONAL 510(k) submission:

- Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation: not applicable as this device is a SW running on a computer not in touch with the patient.
- Sterilization and expiration dating information: not applicable as this device is a SW running on a computer which does not need any sterilization.
- Software Documentation is in **Appendix 5** of this notification

Additional information:

- Relationship between Elekta and 3D Line: 3D Line Research and Development has been recently acquired by Elekta AB (see www.elekta.com), one of the market leaders in Radiation Oncology, so it is now part of this group that includes manufacturing sites (such as Elekta Oncology Systems Ltd in Crawley - UK, Elekta Instruments AB in Stockholm - Sweden, Medical Intelligence in Schwabmunchen – Germany) as well as business units all over the world. Our US agent is Elekta Inc. 4775 Peachtree Industrial Blvd. Building 300, Suite 300, Norcross, GA 30092.

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- Page numbering: we believe we have followed FDA guidelines in terms of page numbering, in order to have a punctual identification of all pages. In respect to certain documents, we kept the original page numbering that must be used in addition to the Document ID. The document ID is then identified at the beginning of each section/appendix. So punctual identification can be achieved by looking at the document ID (e.g. for the system requirement specification document, the ID is SRS-201-3 and can be seen on the top right part of the page) together with the page numbering (bottom left part of the page).

We believe that the enclosed information is sufficient for the Food and Drug Administration to make a determination of substantial equivalence for **ERGO++**. If you have any questions or require any additional information, please contact me (telephone # +39-02-2550161, email address: marco.luzzara@elekta.com, and facsimile #: +39-02-25501642). You can also contact our US agent: Thomas Valentine, Director Quality Assurance and Regulatory Affairs, Elekta Inc. 4775 Peachtree Industrial Blvd. Building 300, Suite 300, Norcross, GA 30092. Phone (770)

670-2548 direct, (404) 797-2537 mobile, (770) 729-1585 fax, email Thomas.Valentine@elekta.com.

Information contained in this notification is confidential, proprietary, and trade secret until released by 3D Line Research and Development S.r.l.. Release of this information is subject to applicable provisions of the Food, Drug, and Cosmetic Act, the Freedom of Information Act, and pertinent regulations in 21 CFR Parts 20 and 800. Should FDA contemplate release of any part of this notification to any third party, 3D Line Research and Development S.r.l. requests a consultation prior to any such release under the provisions of 21 CFR 20.15 and sections affording similar rights.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2008

3D Line Research and Development S.r.l.
% Mr. Thomas Valentine
Director Quality Assurance and Regulatory Affairs
Elenta, Inc.
Peachtree Industrial Blvd., Building 300, Suite 300
NORCROSS GA 30092

Re: K080601
Trade/Device Name: ERGO++
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: February 28, 2008
Received: March 10, 2008

Dear Mr. Valentine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix 2 - Indications for Use Statement and Technical Description of **ERGO++**

510(k) Number (if known): K080601

Device Name: ERGO++

Indications for Use:

ERGO++ is a treatment planning system. It is an accessory to linear accelerators used for radiation therapy. It is indicated for use in the planning of 3 dimensional radiation therapy.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080601